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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C F R § 1 53(b))

Attorney Docket No.	RTI-106
First Inventor or Application Identifier	John R. Bianchi
Title	CERVICAL TAPERED DOWEL
Express Mail Label No.	EK086688289US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents

ADDRESS TO: **Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231**

1. [X] * Fee Transmittal Form (e.g., PTO/SB/17) *(Submit an original and a duplicate for fee processing)*
2. [X] Specification [*Total Pages* 18] *(preferred arrangement set forth below)*
   - -Descriptive title of the Invention
   - -Cross References to Related Applications
   - -Statement Regarding Fed sponsored R & D
   - -Reference to Microfiche Appendix
   - -Background of the Invention
   - -Brief Summary of the Invention
   - -Brief Description of the Drawings *(if filed)*
   - -Detailed Description
   - -Claim(s)
   - -Abstract of the Disclosure
3. [X] Drawing(s) *(35 U.S.C. 113)* [*Total Sheets* 15]
4. Oath or Declaration [*Total Sheets* 2]
   - a. [ ] Newly executed (original or copy)
   - b. [ ] Copy from a prior application (37 C.F.R. .§ 1.63 (d)) *(for continuation/divisional with Box 16 completed*
     - i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b)

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5. [ ] Microfiche Computer Program (*Appendix*)
6. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   - a. [ ] Computer Readable Copy
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ACCOMPANYING APPLICATION PARTS

7. [ ] Assignment Papers (cover sheet & document(s))
8. [ ] 37 C.F.R.§ 3.73(b) Statement *(when there is an assignee)* [X] Power of Attorney
9. [ ] English Translation Document *(if applicable)*
10. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
11. [ ] Preliminary Amendment
12. [X] Return Receipt Postcard (MPEP 503) *(should be specifically itemized)*
13. [X] *Small Entity Statement(s) *(PTO/SB/09-12)* [ ] Statement filed in prior application, Status still proper and desired
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*Prior application information: Examiner*________ *Group/Art Unit:*________

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17. CORRESPONDENCE ADDRESS

[ ] *Customer Number or Bar Code Label* *(Insert Customer No. or Attach bar code label here)* or [ ] *Correspondence address below*

Name	Timothy H Van Dyke	*Address*	Bencen & Van Dyke, P.A., 1630 Hillcrest Street, Orlando, Florida 32803 USA
Telephone	407-228-0328	*Fax*	407-228-0329

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Name (Print/type)	Timothy H. Van Dyke	*Registration No. (Attorney/Agent)*	43218
Signature	[signature]	*Date*	11-1-2000

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TOTAL AMOUNT OF PAYMENT ($)453.00

Complete if Known	
Application Number	N/A
Filing Date	11/1/2000
First Named Inventor	Bianchi
Examiner Name	Unknown
Group/Art Unit	Unknown
Attorney Docket No.	RTI-106

METHOD OF PAYMENT (check one)

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FEE CALCULATION

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101	690	201	355	Utility filing fee	$355.00
106	310	206	155	Design filing fee	
107	480	207	240	Plant filing fee	
108	690	208	345	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($) 355.00

2. EXTRA CLAIM FEES

		Extra Claims	Fee from Below	Fee Paid
Total Claims	22 -20**=	2	X $9.00	= $18.00
Independent Claims	5 -3**=	2	X $40.00	= $80.00
Multiple Dependent				=

**or number previously paid, if greater, For Reissues, see below

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	78	202	40	Independent claims in excess of 3
104	260	204	130	Multiple dependent claim, if not paid
109	78	209	39	**Reissue independent claims over original patent
110	18	210	9	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)98.00

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge – late filing fee or oath	
127	50	227	25	Surcharge – late provisional filing fee or cover sheet.	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	380	216	190	Extension for reply within second month	
117	870	217	435	Extension for reply within third month	
118	1,360	218	680	Extension for reply within fourth month	
128	1,850	228	925	Extension for reply within fifth month	
119	300	219	150	Notice of Appeal	
120	300	220	150	Filing a brief in support of an appeal	
121	260	221	130	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive – unavoidable	
141	1,210	241	605	Petition to revive – unintentional	
142	1,210	242	605	Utility issue fee (or reissue)	
143	430	243	215	Design issue fee	
144	580	244	290	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	690	246	345	Filing a submission after final rejection (37 CFR § 1.129(a))	
149	690	249	345	For each additional invention to be examined (37 CFR § 1.129(b))	

Other fee (specify) _____

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SUBMITTED BY				Complete (if applicable)	
Name (Print/Type)	Timothy H. Van Dyke	Registration No (Attorney/Agent)	43218	Telephone	407-228-0328
Signature				Date	11-1-2000

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STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(c)) -- SMALL BUSINESS CONCERN

Docket Number (Optional): RTI-106

Applicant, Patentee, or Identifier: Bianchi
Application or Patent No.: N/A
Filed or Issued: 11/1/2000
Title: CERVICAL TAPERED DOWEL

I hereby state that I am
☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF SMALL BUSINESS CONCERN Regeneration Technologies, Inc.

ADDRESS OF SMALL BUSINESS CONCERN 1 Innovation Drive, Alachua, Florida 32615

I hereby state that the above identified small business concern qualifies as a small business concern as defined in 13CFR Part 121 for purposes of paying reduced fees to the United States Patent and Trademark Office. Questions related to size standards for a small business concern may be directed to: Small Business Administration, Size Standards Staff, 409 Third Street, SW, Washington, DC 20416.

I hereby state that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention described in:

☒ the specification filed herewith with title as listed above.
☐ the application identified above.
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NAME OF PERSON SIGNING Jamie M. Grooms

TITLE OF PERSON IF OTHER THAN OWNER President, CEO

ADDRESS OF PERSON SIGNING 1 Innovation Drive, Alachua, Florida 32615

SIGNATURE Jamie M. Grooms DATE 11/1/2000

Title of the Invention

CERVICAL TAPERED DOWEL

Background of the Invention

Many advances are being made in the field of orthopedic implants, especially in relation to the treatment of diseases, injuries or defects of the spine. For example U.S. Patent No. 5,814,084 ('084 patent) discloses a diaphysial cortical dowel designed for vertebral fusions, which represents a marked improvement over the conventional implants to date. The dowel of the '084 patent is made of bone, thus it is remodeled by the patient and does not suffer from many of the drawbacks observed with metals and synthetics, e.g., inflammation, weakening of surrounding tissues, and antigenicity. The subject invention builds on the successes in this field, by providing an implant that is shaped for implantation at certain locations of the spine and aids in maintaining the proper curvature of the spine as well.

Summary of the Invention.

The subject invention relates to an implant made of bone that comprises an elongated body having a first and second ends, wherein the elongated body tapers down its length from a point on or proximate to the first end to the second end or a point proximate thereto. The term "proximate" as used herein is intended to mean a point or region located on the elongated body of the implant that is closer to the end to which it corresponds than the opposing end. For example, proximate to said first end would mean a point or region closer to the first end than the second end. Specifically exemplified is an implant substantially shaped in the form of a dowel.

In a another embodiment, the subject implant has a channel formed therethrough to allow for the disposition therein of osteogenic and other biomedical substances. Optionally, the implant has perforations or holes to facilitate the release and delivery of such substances.

In an alternative embodiment, the subject implant comprises a plurality of sections that can be assembled and secured together. As with the other embodiments described herein, the assembled implant can comprise a channel for the disposition of osteogenic and other substances.

The subject implant is designed for implantation into the spine during spinal surgeries, especially spinal fusions (arthrodesis). The taper of the subject invention provides an advantage over conventional implants, as it creates the proper support and angulation to maintain the proper curvature of the spine (lordosis). Accordingly, a further embodiment of the subject invention pertains to a method of performing spinal surgery comprising implanting the subject implant into the intervertebral space in a spinal fusion procedure. Further, the novel use of bone as the material for producing the subject implant provides other advantages. Such advantages include the provision of an implant that is remodeled by the body into autogenous bone, and thereby incorporated into the existing bone structure. This leads to a more desirable result with respect to the strength and integrity of the implant. Further, the subject implant does not have the problem of inflammation at the implant site that is often caused by non-remodelable materials, such as metals or plastics. This inflammation can lead to deterioration of the bone surrounding the implant site, which can cause complications and necessitate follow-up surgeries.

Brief Description of the Drawings

Figure 1 shows side view (Figure 1A) and an end view (Figure 1B) of a starting bone block that is machined to obtain a tapered implant according to the teachings herein, and which comprises holes to engage a securing device.

Figure 2 shows another embodiment of the subject implant that has a threaded outer surface and comprises a channel that provides a space to dispose biologically active substances. Figure 2A shows a side view of this embodiment and Figure 2B depicts a close-up of the threaded surface.

Figure 3 shows another embodiment of the subject implant that comprises an oval channel and whose threads are slightly modified compared to the threads shown in Figure 2. Figure 3A shows a side view capturing the channel of the implant. Figure 3B represents a close-up of the threads machined on the exterior of the implant. Figure 3C represents an end-view of this embodiment. Figure 3D shows a side-view of this embodiment that is rotated as to show the side walls of the implant adjacent to the channel.

Figure 4 shows a further embodiment of the subject implant that comprises a wedge-like end to aid in manipulating the implant. Figure 4A shows a side view which depicts the channel and wedge-like end. Figure 4B shows a perspective view of this embodiment. Figure 4C shows an end-view of the wedge-like end. Figure 4D shows a side view that is rotated as to show the side walls of the implant adjacent to the channel.

Figure 5 shows a further embodiment of the subject implant that tapers from one end to the other but has a region in the middle of the implant that is more narrow than either end.

Figure 6 shows a further embodiment of the subject implant that comprises a slot formed on the wider of the two ends. Figure 6A is a perspective view of this embodiment. Figure 6B is a side view of this embodiment. Figure 6C is an end-view of the wider end of this embodiment.

Figure 7 shows an end-view (Figure 7B-C) and side view (Figure 7A) of several drives for securing the subject implant into place.

Figure 8 shows side views (Figures 8A-B) and end view (Figure 8C) of a further embodiment of the subject implant.

Figure 9 shows a further embodiment of the subject implant that comprises pinch cut out for engaging a securing device. Figure 9A is a side view of an embodiment that

has a channel and smooth exterior. Figure 9B is an end view of the embodiment shown in Figure 9A. Figure 9C is a side view of the embodiment of Figure 9A which has a threaded exterior surface.

Figure 10 shows a perspective view of another embodiment of the subject invention that comprises a number of separate pieces (Figure 10A) that are assembled into a single unit (Figure 10B).

Figure 11 shows a perspective view (Figure 11A), an end-view (Figure 11B), a cross-sectional view (Figure 11C), and a side view (Figure 11D) of another embodiment of the subject implant that is perforated to facilitate delivery of biologically active substances.

Figure 12 shows a perspective view (Figure 12A), an end-view (Figure 12B), a cross-sectional view (Figure 12C), and a side-view (Figure 12D) of an embodiment of the subject implant which is a variation of the embodiment shown in Figure 11.

Figure 13 depicts an example of a bone that is an appropriate source for deriving an implant having a wedge-like end.

Figure 14 represents a schematic for procuring a bone block from the bone depicted in Figure 13, which can then be machined to form an implant according to the teachings of the subject invention.

Description of the Preferred Embodiments

Turning now to the drawings, Figure 1A-B show an example of a bone block **100** that is then tapered according to the teachings of the subject invention. The dashed lines **A** depict the tapering of the bone block, which can be accomplished by conventional machining methods, e.g., with a lathe and in particular, a CNC lathe. Holes **105** are

drilled into the bone block via a drill to engage a securing device for positioning of the implant of the subject invention into the spine. Preferably, 4 holes are drilled in a square configuration suitable for engaging a specially adapted securing device having four prongs for insertion into holes **105**. Typically, the subject implant is secured by rotation. See Figure 1B. Machining attachment hole **110** is formed in the bone block **100** which provides a means for the block to be positioned in a machine such as a mill or lathe to hold the block steady during machining, to ensure proper alignment, and to permit rotation of the workpiece during machining.

In Figure 2A-B, there is shown another embodiment **200** of the subject implant. As shown in Figure 1, embodiment **200** comprises holes **205** for engaging a securing and driving device. Further, this embodiment comprises a channel **220** that preferably transverses completely through the implant. Channel **220** provides a space into which an osteogenic material can be disposed to aid in the healing and bone formation process. Also, the inventors have discovered that provision of the channel **220** aids in release of bone morphogenetic proteins (BMP) naturally present in the bone used for producing the subject implant and better contact of adjacent vertebrae with the osteogenic material within said dowel. In addition, in embodiments of this invention, channels, pores or the like may be formed, preferably connecting the exterior of the implant with the channel, to better induce seepage of growth factors from the osteogenic material in the channel or in the bone into the surrounding tissue. Embodiment **200** also comprises a machining attachment hole **210**. Various dimensions of the implant are noted in Figure 2A-B, represented by the letters **B-G**. The skilled artisan will readily appreciate that these dimensions can be adapted to suit various sized patients, including infants, children, and adults. The following values are to be viewed as preferred values. Length **B** can range from about 5 to about 25 mm, and preferably from about 10 to about 15 mm. The root diameter **C** can range from about 3 to about 15 mm, and preferably from about 4 to about 11 mm. The taper angle **D** can range from about 1 to about 8 degrees, and preferably from about 3 to about 5 degrees. **E** can range from about 0.3 mm to about 1mm, and preferably from about 0.4 mm to about 0.6 mm. The radius **F** of the thread profile can range from about 0.3 mm to about 1.3 mm, and preferably from about 0.5 mm to about

0.9mm. The pitch **G** of the thread profile can range from about 0.08 to about 2 mm, and preferably from about 1 mm to about 1.8 mm.

In Figure 3A-D, there is shown a further embodiment **300** of the subject implant that is similar to embodiment **200** except that the channel **320** is oval in shape and the thread profile is slightly modified. The oval shape of the channel **320** is achieved by drilling a circular hole through the implant, and then drawing an appropriately dimensioned broach through the circular hole. Preferably, the broach has disposed thereon cutting teeth which change in shape as the diameter of the broach increases from a circular to an oval circumference. Embodiment **300** also comprises a machining attachment hole **310**. Those dimensions noted in Figures 3A-D have similar values to that described above for embodiment **200** unless otherwise indicated. Dimension **H** comprises the length of the channel **320** which can range from about 4 to about 8 mm. It represents the angular relation of the holes **305** from the center axis of the implant. As shown, holes **305** are preferably placed 45 degrees above and below the x-axis. Figure 3B shows the thread profile comprising a ridge **J**, which can range from about 0.05 mm to about 0.15 mm. Further, embodiment **300** comprises a machining attachment hole **310**.

Figure 4A-D, show a further embodiment **400** of the subject implant which comprises oblique sides **415** thereby forming a "roof-top" or wedge-like shape on end **410** of the implant to engage a securing device, wherein the securing device is shaped to conform to end **410**. Embodiment **400** comprises a channel **420**. Further, the dimensions noted in Figure 4A-D have the same values as above, unless otherwise indicated. Embodiment **400** comprises a substantially planar or flat end **425** having a dimension **L** toward which oblique sides **415** slope and connect. Dimension **L** preferably ranges from 0.5 to about 5 mm. A securing device hole **430** is formed into the wedge end which is designed to engage to a securing device to thereby further stabilize the implant on the securing and driver device during implantation. Dimensions **M** and **N** preferably range from about 0.5 mm to about 7 mm. More preferably, dimension **N** is equal to or larger

than dimension **M**. Wedge angle **P** preferably ranges from about 45 to about 90 degrees, and preferably is set to a standard style angle to match a reciprocal angle on a driver tool.

It is appreciated in the art that human donor tissue is extremely limited in supply. Thus, it is always advantageous to develop methods of maximizing the use of donor tissue. With this goal in mind, it was discovered that the use of the natural architecture of certain bones in the body are suitable for providing a wedged end as described above for embodiment **400**. For example, the tibia comprises an anterior ridge along a substantial portion of its length. It was found that excising block sections along such a ridge can provide oblique sides, thereby avoiding having to machine and discard precious bone material to produce such oblique sides, while preserving donor bone stock for other applications. Where donor bone is less scarce, as in the use of xenograft bone stock, (including but not limited to bovine, ovine, equine, canine or the like) or if allograft bone is in abundant supply, use of the wedge shaped driving structure is less critical. Where used, however, the wedge-shaped driving structure fits conveniently into a complementary driver device for rotation of the implant.

In an alternative embodiment, as shown in Figures 13 and 14, a method of procuring the subject implant comprises obtaining a long bone, such as the tibia **1300**, and cutting off the ends **1310** and **1320** from the elongated central portion (dashed lines **AA**). Figure 14 shows an end-view of the resulting central portion section produced after excision of the end portions **1310** and **1320**. At this point, sections (dashed lines **BB**) along the ridge **1340** of the tibia are excised which comprise a wedge end as a result of the natural architecture of the bone. Those skilled in the art will understand that this method can be applied to other bones in the body having a desired architecture.

In Figure 5, there is shown a further embodiment **500** of the subject implant that tapers from one end to the other but has a region in the middle of the implant **505** that is more narrow than either end. Embodiment **500** also preferably comprises oblique sides **515** and a securing device hole **530**.

In Figure 6A-C, there is shown another embodiment **600** of the subject implant having a slot **635** formed on the wider of the two ends of the implant. The slot **635** is designed to engage a securing and driving device, such as, for example, a flat-head screwdriver. As in other embodiments, embodiment **600** comprises a channel **620** and a securing device hole **630**. Dimensions **B**, **D**, **H**, and **O** shown in Figure 6A-C, have similar values as described above.

In Figure 7A-D, there are shown further embodiments of the subject implant that comprises a peg **705** contiguous with and extending from end **750**, the wider of the two ends of the implant. The peg acts as driver to turn and secure the implant when engaged to a securing device. The peg device may be round for being driven by a collet, or may be square or otherwise shaped for secure torquing by a reciprocal driving means. Figure 7B shows an end-view of the narrower end **755**. Figures 7C and D show various alternatives for the shape of the peg, e.g., square and hexagonal. The skilled artisan will appreciate other appropriate shapes can be used, e.g. octagonal, triagonal, etc. In addition, it will be appreciated that the drive means may be recessed into the implant and driven by an appropriately shaped driver.

In Figure 8A-C, there is shown another embodiment **800** of the subject implant that comprises both a wedge-like end **810** and a raised vertex **805** to further aid in engaging a securing device. Embodiment **800** comprises a securing device hole **830** as well. Figure 8C shows an end-view of embodiment **800** showing the raised vertex **805**, securing device hole **830**, and the oblique sides **815**. The value of **D** is the same as that described above. Preferably, as shown in Figure 8A, the implant comprises a channel **820**.

Figure 9A-C show a further embodiment **900** of the subject invention that comprises two or more pinch cut outs **905** from the edge of the wider of the two ends **950** of the implant. The pinch cut outs **905** act to engage a securing device for securing the implant in the patient. Figure 9A shows a version of the embodiment **900** that does not have threads disposed on its surface. Figure 9B shows an end-view of the wider end **950**,

which depicts two pinch cut outs **905** positioned on opposing sides of the implant. Figure 9C shows a threaded embodiment. Figure 9D shows an embodiment that comprises a channel **920** and a narrower stepped portion **930** at its wider end **950**.

Those skilled in the art will appreciate that the subject implant does not necessarily comprise threads. However, threads are preferred in most cases, as they aid in securing the implant in the patient. Rotation of the subject implant results in the threads digging into the adjacent bones thereby forming a tight contact.

In Figure 10A-B, there is shown another embodiment **1000** of the subject implant that is comprised of two or more sections that are assembled into a single unit. Embodiment **1000** comprises a first section **1004** and a second section **1005** that are placed contiguous to each other and then secured together by pins **1010**. The pins **1010** may be formed from any appropriate material, including but not limited to cortical bone, titanium, stainless steel, hydroxyapatite, bioactive glass, polylactic acid and like polymers. The second section has a slot **1015** formed thereon for engaging a securing device, as well as a securing device hole **1030** for further stabilization on the securing device during implantation. Figure 10B shows the embodiment **1000** as assembled. In addition to the slot **1015** and the securing device hole **1030**, Figure 10B illustrates the formation of a channel **1020** when the implant is assembled. Those skilled in the art equipped with the teachings herein will appreciate that the second section **1005** comprising the slot **1015** could be configured to have formed thereon any of the other driver means described herein, e.g., wedge, raised ridge, peg, pinch, 4-pin, etc.

Figure 11A shows a perspective view of further embodiment **1100** of the subject implant, having a tapered body resulting in a smaller diameter for the front end **1110**, and a larger diameter for the back end **1120**. The back end **1120** comprises a hex drive **1130** formed therein for insertion and rotation of the implant. Implant **1100** defines a channel **1140** for use of packing biologically active substances. Holes **1150**, which radiate from the channel **1140** to the cortical surface **1160**, allow the biologically active substances to penetrate through the entire implant **1100**. Figure 11B is an end plan view of implant

1100 showing the back end **1120** along with the hex drive **1130**. Figure 11C depicts a transverse section of implant **1100** along the **AA** axis shown in Figure 11B. The hex drive **1130** is shown running from the front end **1110** to the back end **1120**. Figure 11D shows a side view of implant **1100**, holes **1150**, and screw threads **1170** which are inscribed from the front end **1110** to the back end **1120**. The screw threads **1170** ease insertion and help to hold the implant in place.

Figures 12A-12D show an alternate embodiment of the cervical tapered dowel depicted in Figures 11A-11D. Figure 12A shows a perspective view of implant **1200**, having a tapered body resulting in a smaller diameter for the front end **1210** and a larger diameter for the back end **1220**. The back end **1220** contains an instrument hole **1230** along with a score mark **1240** for use with an insertion device to provide torque to the implant. Implant **1200** contains a channel **1250** for packing biologically active substances along with holes **1260** that radiate from the channel **1250** to the cortical surface **1270**. Figure 12B is an end plan view of implant **1200** showing back end **1220** along with the instrument hole **1230** and the score mark **1240**. Figure 12C depicts a transverse section of implant **1200** along the **AA** axis shown in Figure 12B. The instrument hole **1230** is shown extending partially through the implant into the channel **1250**. Figure 12D shows a side view of implant **1200**. The screw threads **1280** ease insertion and help the implant retain its position once implanted.

It will further be appreciated from the present disclosure that the implant may be contacted with cells prior to implantation. For example, bone implants according to this invention may be cultured with stem cells, fibroblasts, muscle cells, neuronal cells or the like or simply contacted therewith or be infused therewith prior to implantation. Preferably, the cells that are contacted with the implant are stem cells, such as those known in the art or which become known hereafter. For example, human mesenchymal or other stem cells, such as those disclosed in any of US Patent Nos. 5,486,359; 5,811,094; 5,197,985; 5,591,625; 5,733,542; 5,736,396; 5,908,784; 5,942,255; 5,906,934; 5,827,735; 5,962,325; 5,902,741; 4,721,096; 4,963,489; (all of which are hereby incorporated by reference), may be contacted with, infused into or cultured on the

implants of the present invention. The plurality of holes in the implant of this invention thus permit for interpenetration of such cells into the interior of the implant prior to implantation, and from the interior of the implant, to assist in remodeling, subsequent to implantation.

Alternatively, perforations or holes can be formed in the subject implants, which can control and improve the release and delivery of biologically active substances loaded in the channel, or otherwise infused, embedded or coated on or in the implants. Naturally, the rate of release will be dependent on the size and number of holes provided. As discussed above, the channel of the subject dowels can be packed with various biologically active substances, including, but not limited to, growth factors, antibiotics, nucleic acids, proteins, peptides, antineoplastics, and anti-inflammatory compounds, and the like. Furthermore, the plurality of holes taught herein can facilitate the migration and growth of cells and tissues into the implant. It will be appreciated that any appropriate carrier may be used in association with these biologically active substances, including, but not limited to, gelatin, collagen, mixtures thereof, synthetic compositions, biologically resorbable pastes and the like. Furthermore, the composition may comprise a bone paste composition comprising cortical bone chips, cancellous bone chips, demineralized bone matrix powder (DBM), bioactive glass or other ceramics, growth factors, nucleic acids, proteins, peptides, carbohydrates, lipids and the like. Preferably, the substance packed in the canal is an osteogenic substance and/or comprises tissue regenerating growth factors. See, for example, WO98/40113, herein incorporated by reference. Optionally, or in addition to packing the canal, the subject implants can be infused, soaked and/or coated with various biologically active substances.

Example: Procedure for Procuring an Implant having a Wedged End from a Human Tibia

Equipment

Sherline Mill with 3" vice attached to cross table

Modified Sherline machining lathe with tail stock and tooling bit

Modified Sherline lathe with threading attachment
Core Cutters, 12mm and 14mm
3mm drill bit
#0 starter drill
Dial calipers
Fine toothbrush
Scraping tool

Procedure

An appropriate size cutter was loaded in the chuck of the Sherline mill. The tibia segment was clamped in the vice on the mill table with the anterior of the segment facing up and aligned properly and tightened, and the cutter was aligned to the segment. The motor assembly was adjusted to about 200 RPM, and the cutter was lowered down to the bone and cut through the segment. The cutter was retracted to its original position and the cut dowel was removed from the cutter. The foregoing was repeated until all of the dowels were cut.

To form the wedge end of the dowel, a cut dowel as described above was placed with the anterior end facing the tooling bit in the chuck of the machining lathe and tightened. The lathe motor was turned on and the end of the dowel was machined to form 3.5mm oblique side on the end. Using the center drill in the tail-stock, a starter hole was drilled in the end of the dowel. This operation was repeated until all of the dowels were machined with the oblique side and had the starter hole drilled therein.

The ends of machined dowels opposite the oblique sides were flattened and cancellous bone was removed. To accomplish this, each dowel was individually placed into the chuck with the posterior end of the dowel facing the tooling bit and tightened. The end of the dowel was machined until all the cancellous bone was removed and the dowel was flat. The dowel was then removed from the chuck and measured to determine if the length was at a desired length and to determine whether more bone needed to be

removed. Using the center drill in the tail stock, a starter hole in the flattened end of the dowel was drilled. This procedure was repeated for all of the machined dowels. Next, the 3mm drill bit was secured in the chuck in the tail-stock and tightened. A dowel with the 3.5 mm flat was placed in the chuck facing the drill bit and tightened. The tail-stock was advanced forward until the tip of the drill bit was about 1mm from the end of the dowel and the tail-stock was tightened to the lathe bed. The motor was activated and the drill bit was advanced into the dowel to form a hole 6mm in depth. This procedure was repeated for all of the dowels.

The dowels having the oblique sides, flattened end and holes drilled on both ends were then subjected to the threading lathe. The dowel was placed in the threading lathe and tightened. The air motor was activated with the milling cutter attached and advanced into the dowel until lightly touching the dowel. The threading handle was turned to move the cutter assembly to the right until it cleared the dowel. The cutter was advanced forward to remove the desired amount of bone to achieve the desired dowel diameter. The foregoing procedure was repeated for all of the dowels. Using a burring tool or a scraper, any burrs present were removed from the dowel. A fine tooth brush was used to brush the threads on the dowel to remove any fine burrs.

The teachings of all of the references cited throughout this specification are incorporated herein by this reference to the extent that they are not inconsistent with the teachings herein. Thus, for example, a device made from metal is known for application to the cervical spine (see US Patent 5,782,919; US Patent 5,669,909, herein incorporated by reference for this purpose). The present invention provides an improvement to such devices in that the bone material of the present implant is remodelable, such that autogenous bone replaces implant bone over time to induce a permanent fusion, while metallic implants frequently require removal or cause stress shielding, ultimately causing the implant to fail. It should be understood that the examples and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application and the scope of the appended claims.

Claims

What is claimed is:

1. A biomedical implant designed for implantation into a spine of a patient comprising an elongated body having first and second ends, said elongated body being tapered such that tapering begins at a first position on or proximate to said first end and continues down the length of the elongated body down to a second position on or proximate to said second end, wherein said implant is comprised of cortical, cortico-cancellous, or cancellous bone.

2. The biomedical implant of claim 1 wherein said elongated body defines a substantially dowel-like shape.

3. The biomedical implant of claim 1 wherein said first end comprises one or more insertion holes formed into said first end such that said insertion holes are oriented along the longitudinal axis of said biomedical implant, wherein said holes are configured to engage a securing device.

4. The biomedical implant of claim 1 wherein said one or more insertion holes define a circular, triangular, quadrangle, pentagonal, hexagonal, heptagonal or octagonal shape, or combination thereof, and said securing device comprises inserts configured to match the shape of said insertion holes.

5. The biomedical implant of claim 1 wherein said first end defines a wedge shape for engaging a securing device.

6. The biomedical implant of claim 4 wherein said wedge shape comprises two or more substantially planar sections that are angled obliquely in relation to the exterior surface of said elongated body.

7. The biomedical implant of claim 4, wherein said wedge shape corresponds to the natural architecture of the bone from which said biomedical implant is made.

8. The biomedical implant of claim 1, wherein said first end has two or more pinch cut outs formed thereon.

9. The biomedical implant of claim 1, wherein said implant comprises a channel formed through said elongated body such that said channel is positioned transverse to the longitudinal axis of said implant, said channel being adapted to have a biologically active substance disposed therein.

10. The biomedical implant of claim 1, wherein said first end defines a peg portion extending longitudinally therefrom, said peg portion configured to engage a securing device.

11. A biomedical implant designed for implantation into the spine of a patient comprising two or more separate sections that are configured such that said two or more separate sections can be joined together, wherein upon said two or more separate sections being joined, an implant is formed comprising an elongated body having a first and second ends, said elongated body being tapered such that tapering begins at a first position on or proximate to said first end and continues down the length of the elongated body down to a second position on or proximate to said second end.

12. The biomedical implant of claim 11, wherein said implant is comprised of cortical, cortico-cancellous, or cancellous bone, or a combination thereof.

13. The biomedical implant of claim 11, wherein said two or more sections comprise joining holes formed therein such that said two or more sections are joined together by insertion of pins through said joining holes.

14. The biomedical implant of claim 13, wherein said pins are comprised of cortical bone.

15. A method of producing a biomedical implant that comprises an elongated body having a first and second ends wherein said first end comprises two or more oblique sides, said method comprising obtaining a bone having a ridge naturally formed thereon and excising bone block sections from said bone at an angle substantially perpendicular to said ridge.

16. The method of claim 15, wherein said bone is selected from a bone selected from the group consisting of femur, tibia, fibula, humerus, radius and ulna.

17. The implant according to claim 1 comprising a plurality of holes formed therein, optionally connecting to a central channel formed in said implant, to aid in delivery of a biologically active substance disposed on or within the implant to surrounding tissue.

18. The implant of claim 17 wherein said biologically active substance comprises one or more substances selected from the group consisting of cells, growth factors, antibiotics, nucleic acids, proteins, peptides, antineoplastics, and anti-inflammatory compounds.

19. The implant according to claim 1 formed substantially from human, allograft cortical bone or xenograft bone.

20. A method of treating a defect or injury to the spine comprising obtaining a biomedical implant, said biomedical implant comprising an elongated body having first and second ends, said elongated body being tapered such that tapering begins at a first position on or proximate to said first end and continues down the length of the elongated body down to a second position on or proximate to said second end, wherein said implant is comprised of cortical, cortico-cancellous, or cancellous bone; and implanting said implant into a location in the spine to effect support at that location.

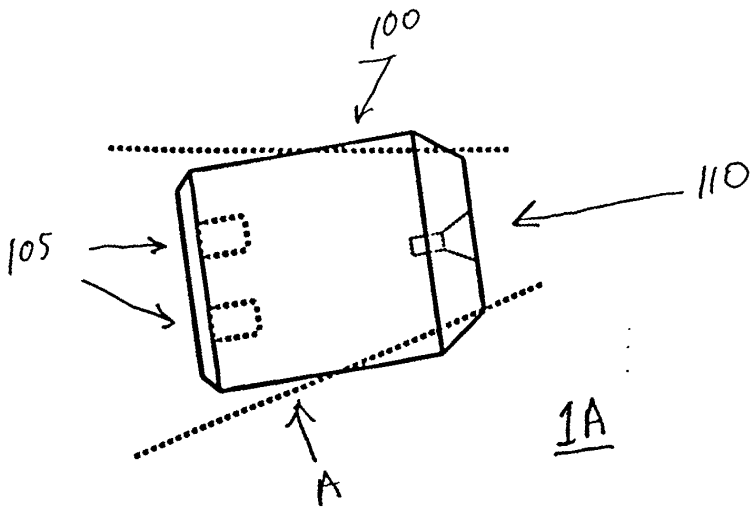
21. The method of claim 20, wherein said biomedical implant comprises two or more sections joined together.

21. The method of claim 20, wherein said implant comprises a channel formed through said elongated body such that said channel is positioned transverse to the longitudinal axis of said implant, said channel being adapted to have a biologically active substance disposed therein.

22. A method for fusing vertebrae which comprises making a space between the vertebrae to be fused, and inserting into said space a biomedical implant, said biomedical implant comprising an elongated body having first and second ends, said elongated body being tapered such that tapering begins at a first position on or proximate to said first end and continues down the length of the elongated body down to a second position on or proximate to said second end, wherein said implant is comprised of cortical, cortico-cancellous, or cancellous bone.

Abstract of the Disclosure

Disclosed herein are biomedical implants, and methods of using same, that are derived from bone. Particularly exemplified are implants having a tapered dowel shape that are useful for implantation in the spine, and especially in the cervical region of the spine. The taper of the implants disclosed herein provides an advantage over conventional implants, as it creates the proper support and angulation to maintain the proper curvature of the spine. Optionally, the implants taught herein are associated with osteogenic materials or other biomedical substances.



1A

Figure 1

1B

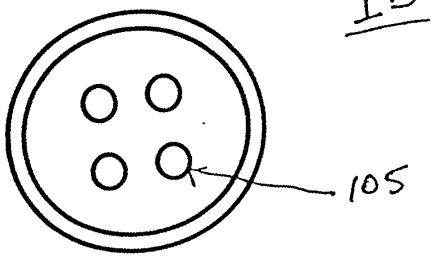


Figure 2

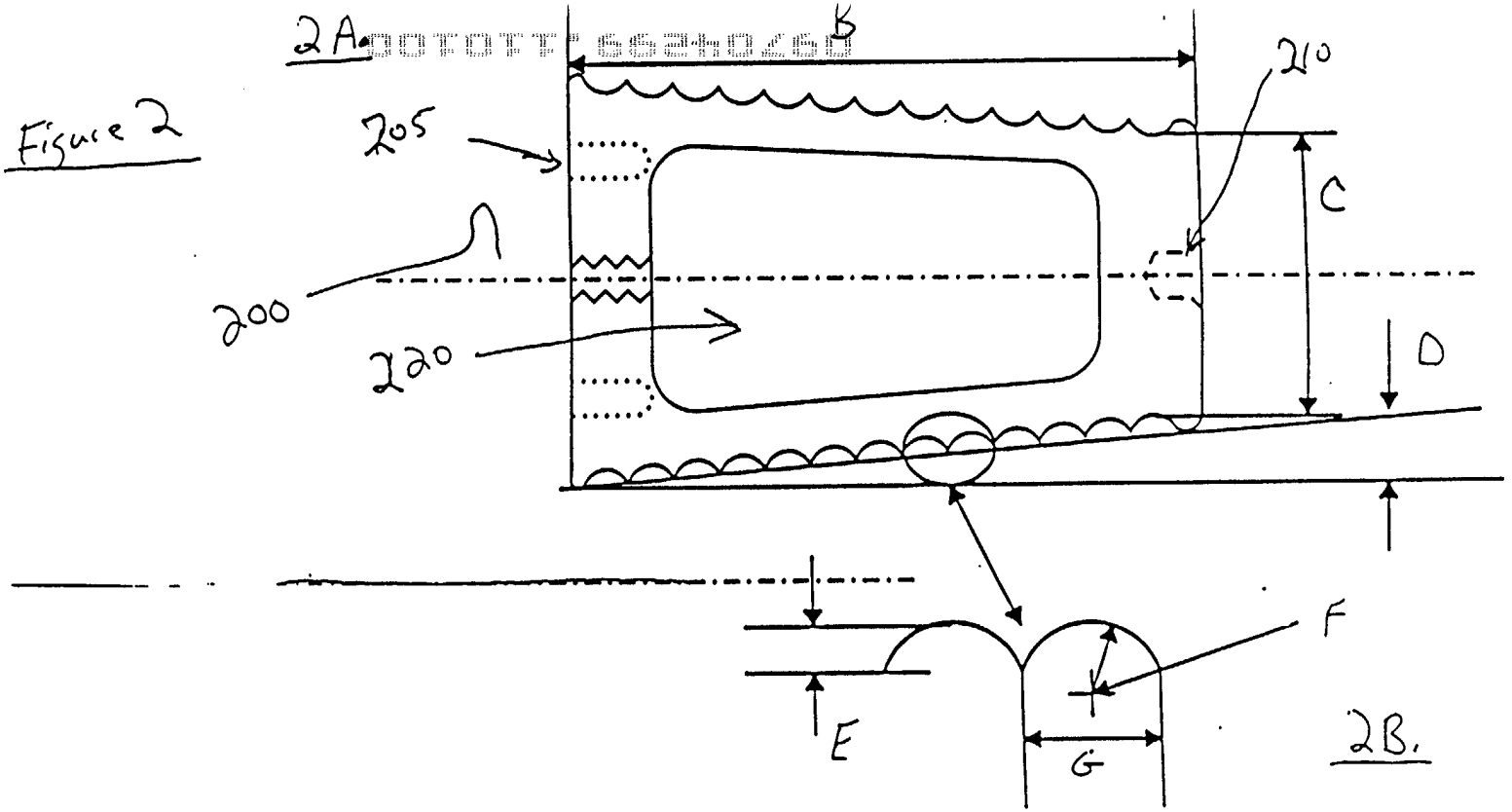


Figure 3.

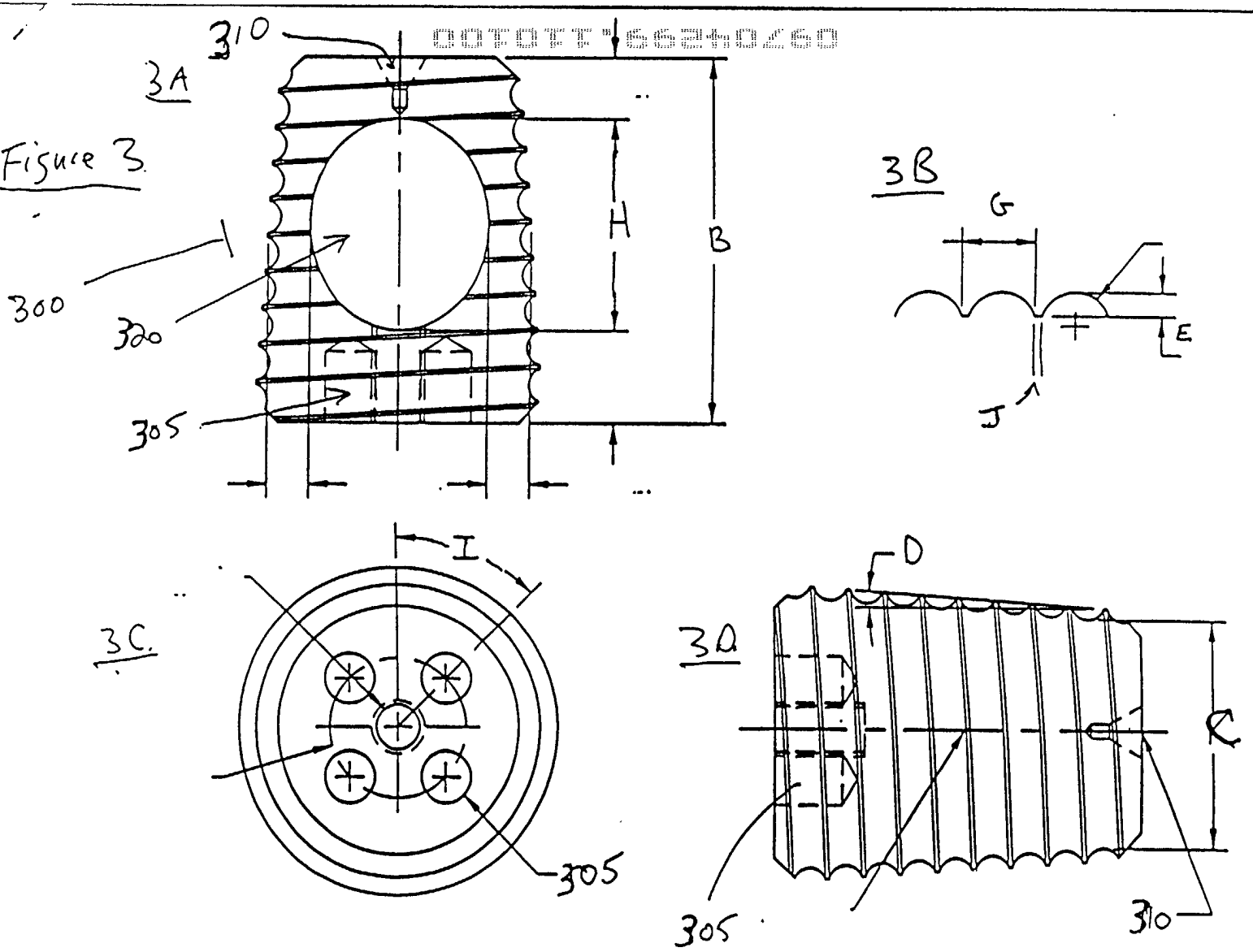
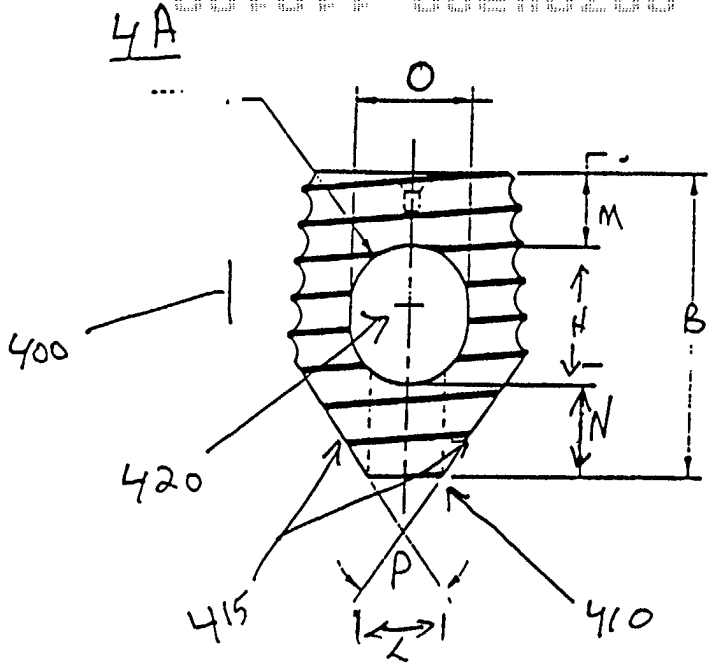
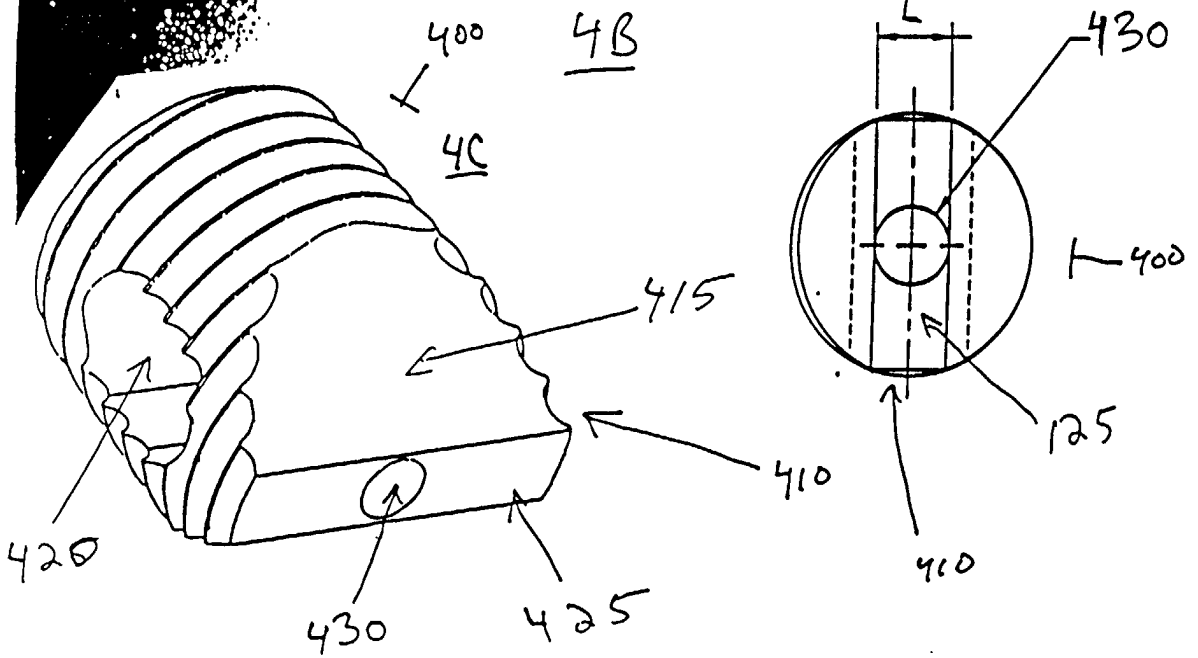


Figure 4


4A
O
M
H
B
N
400
420
415
P
L
410


400
4B
4C
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430
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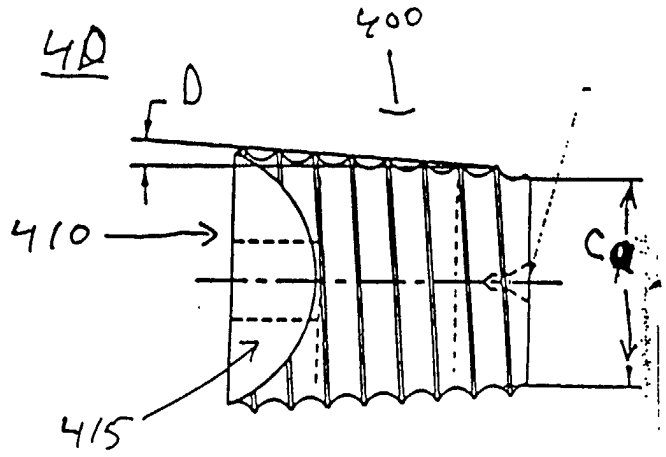
L
430
400
125
410


4D
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D
410
C
415

Figure 5

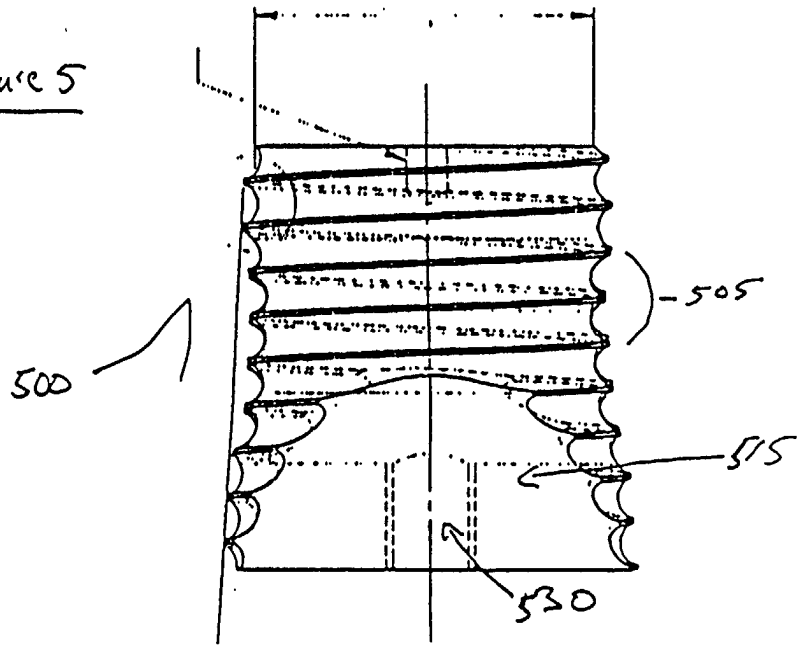
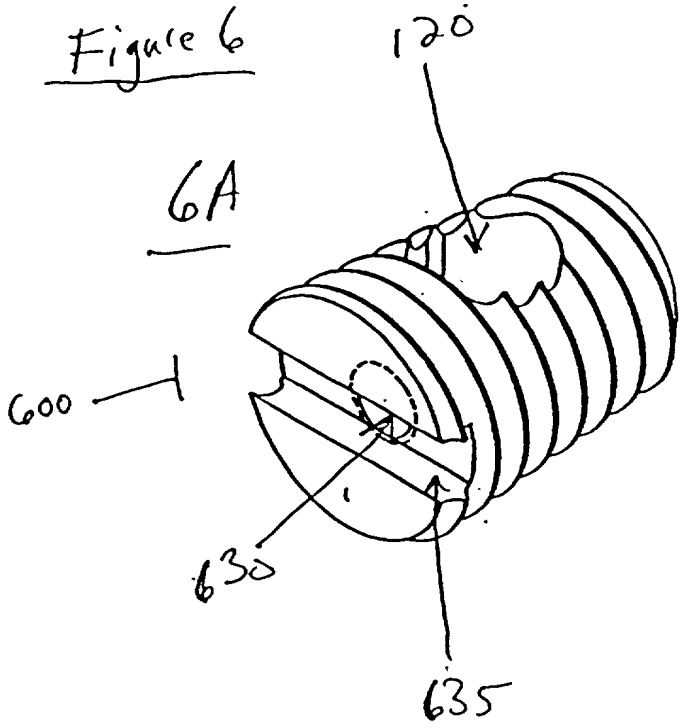


Figure 6

6A



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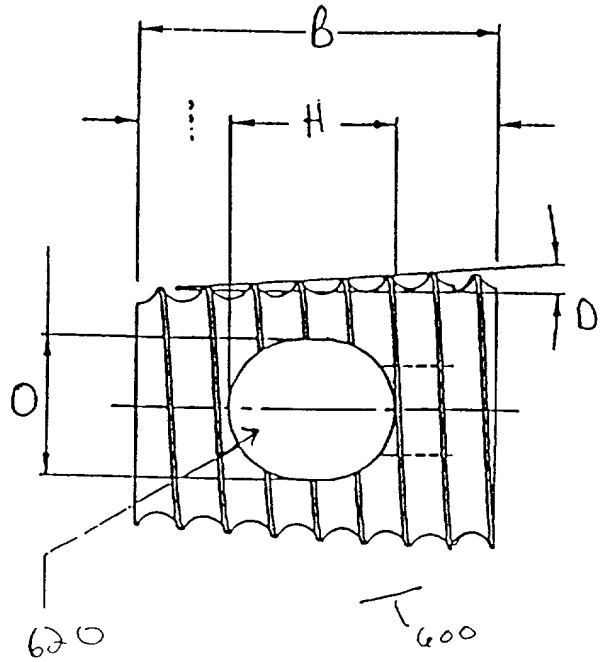

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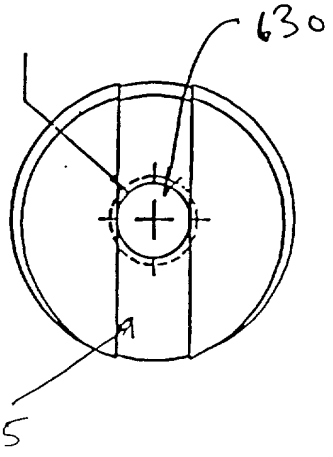
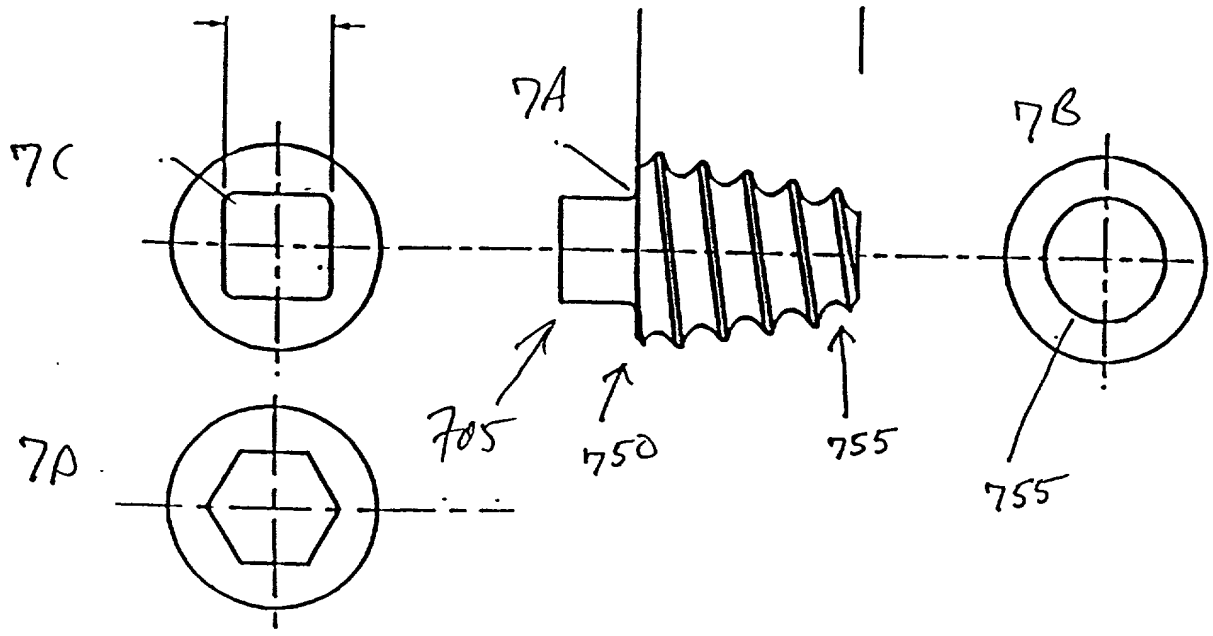


Figure 7



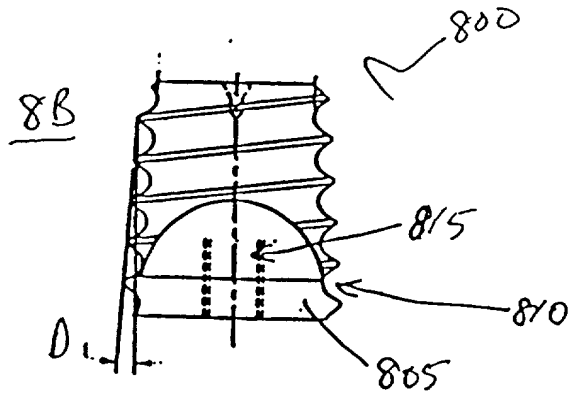
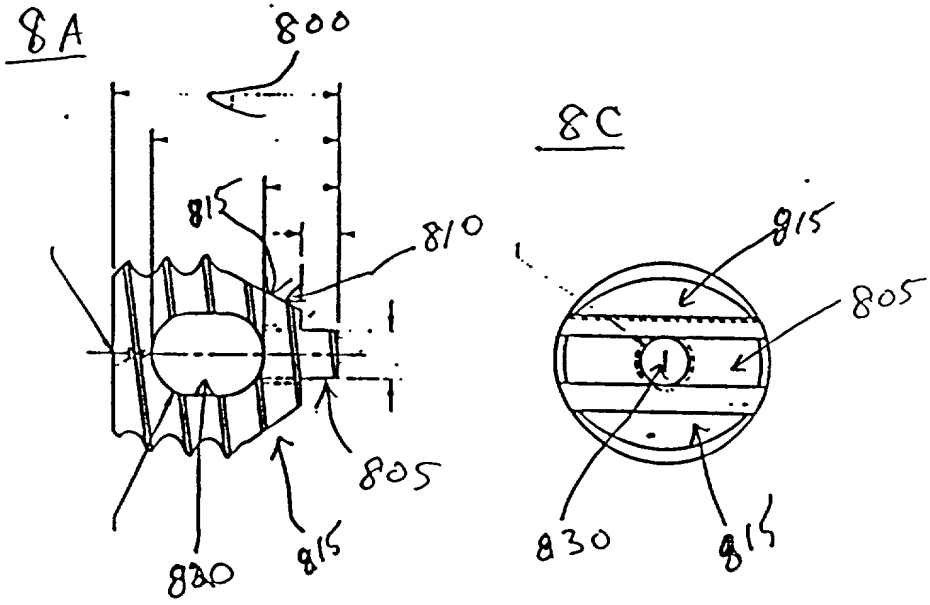

8B
800
815
810
D1
805

Figure 8


8A
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815
810
805
820
815
8C
815
805
830
815

Figure 9

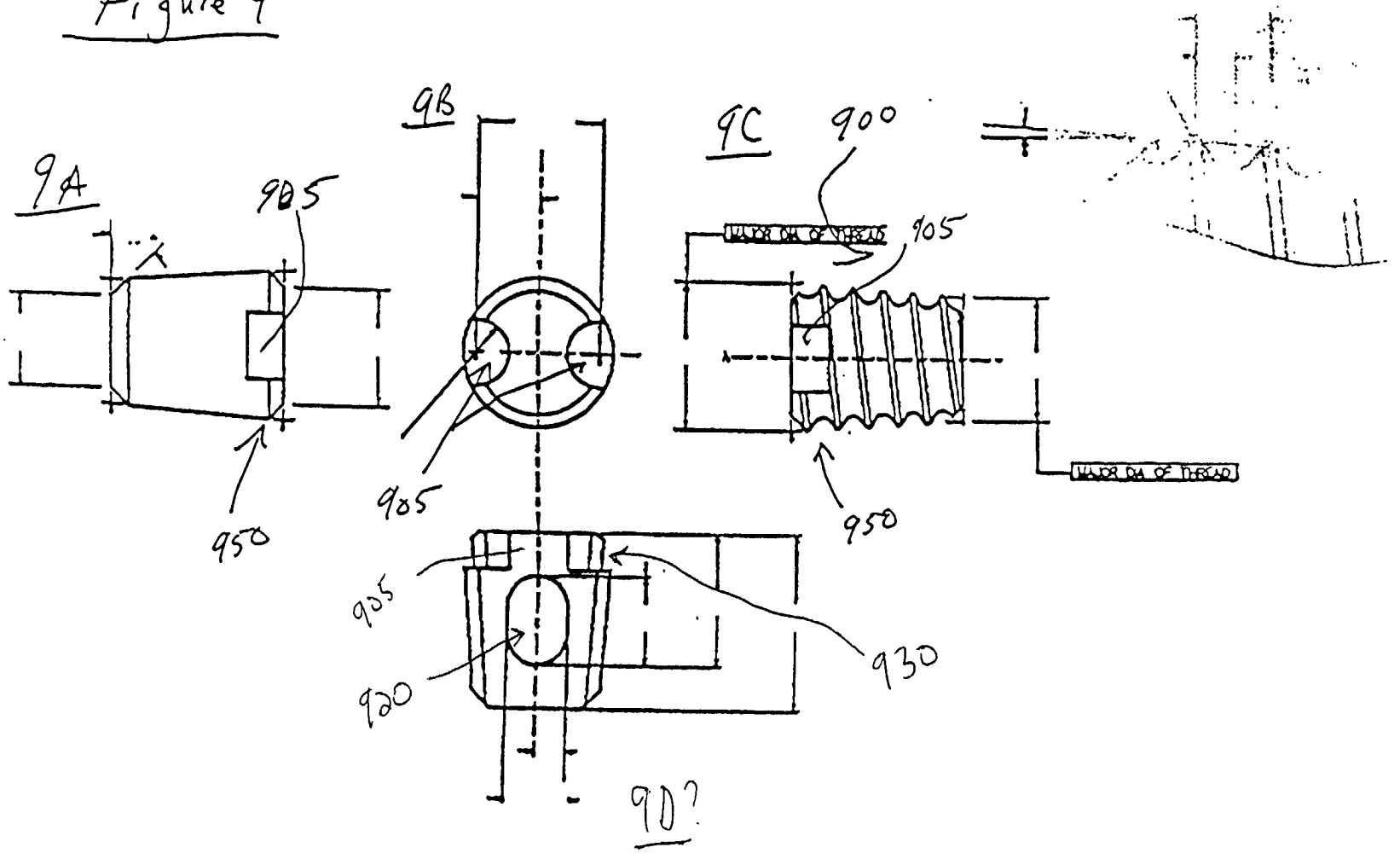


Figure 10

10A

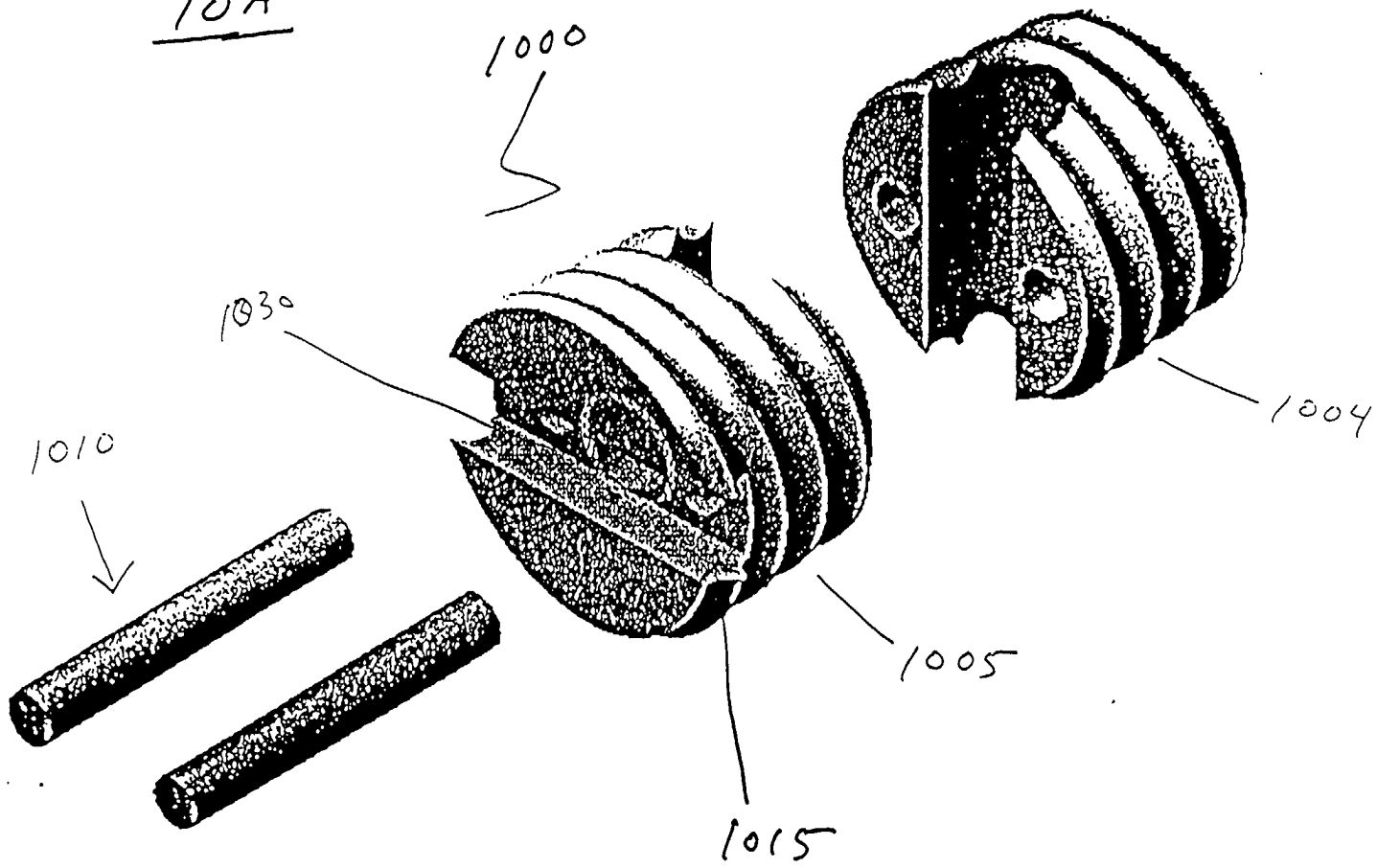


Figure 10B

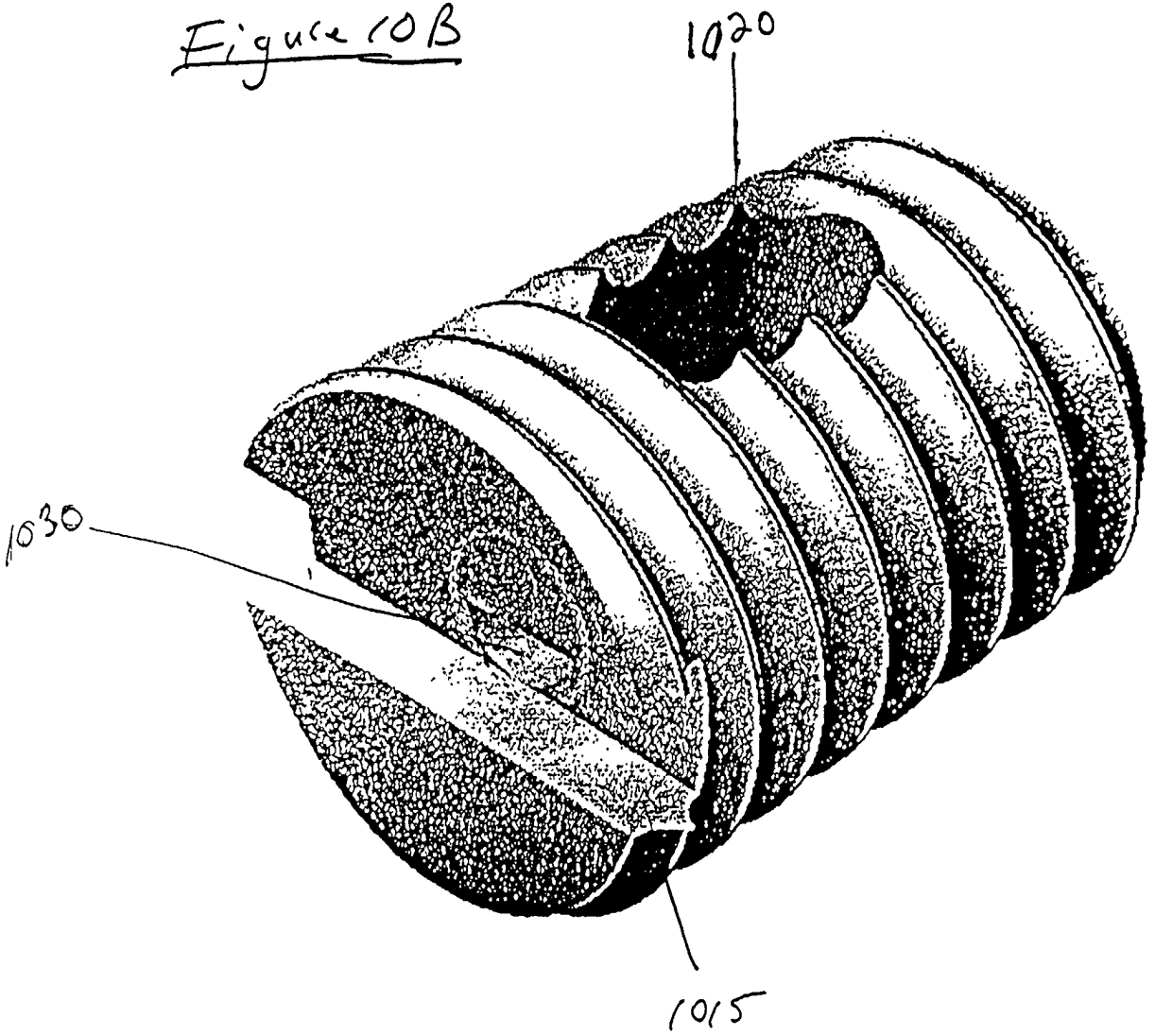
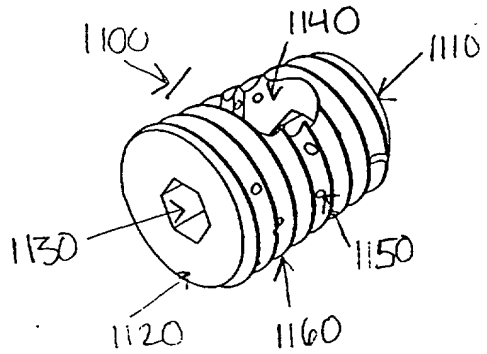


Figure 11A



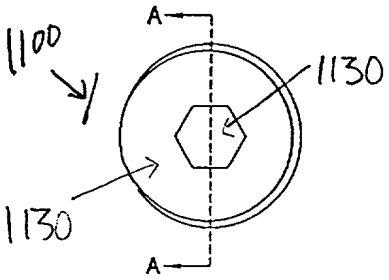
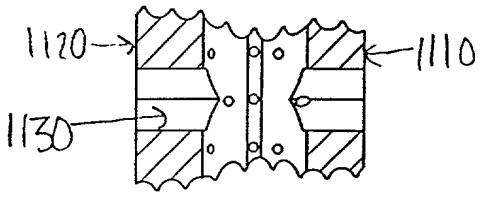


Figure 11B

Figure 11C



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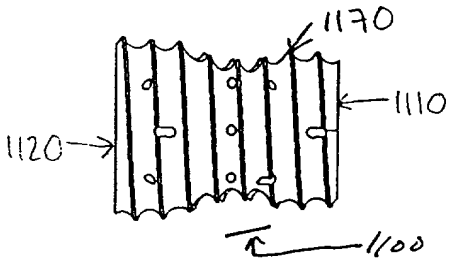
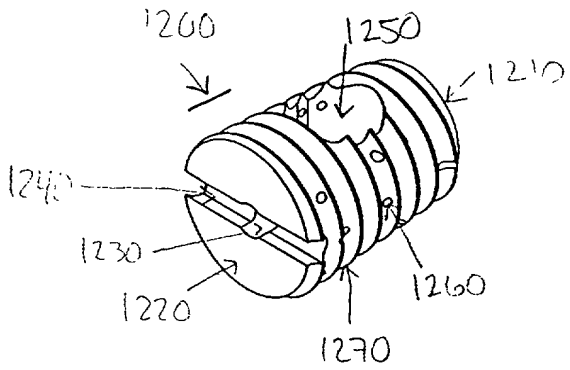


Figure 11D

Figure 12A



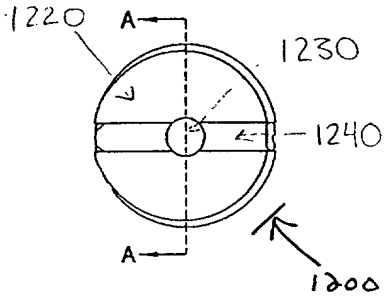
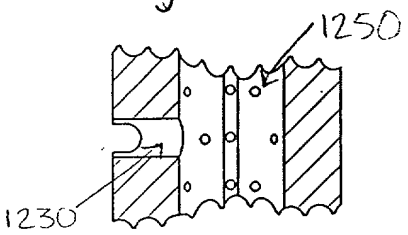


Figure 12B

Figure 12C



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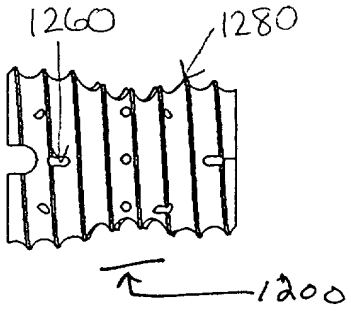


Figure 12D

Figure 13

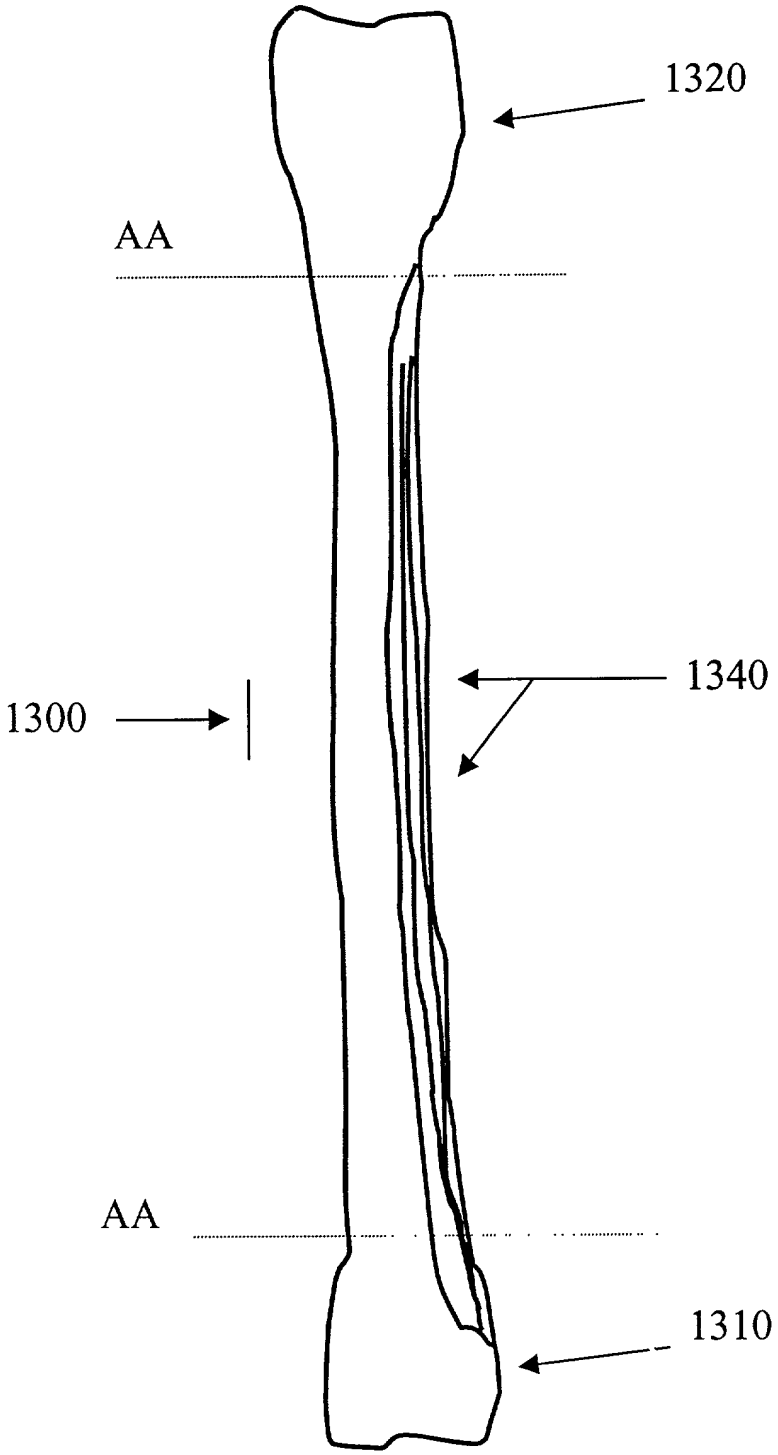
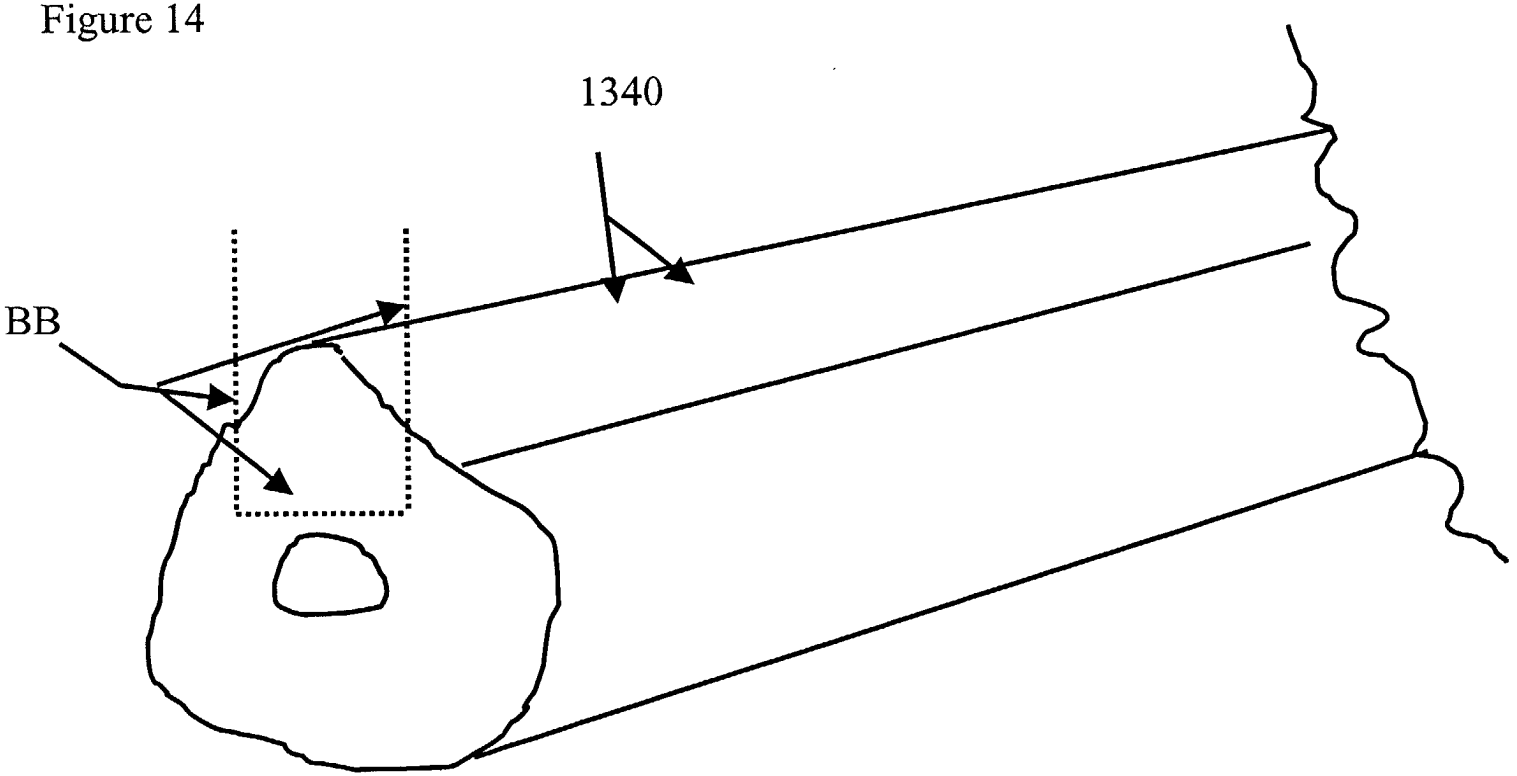


Figure 14



PATENT APPLICATION

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION ATTORNEY DOCKET NO. RTI-106

As a below named inventor, I hereby declare that:

My residence/post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

CERVICAL TAPERED DOWEL

the specification of which is attached hereto unless the following box is checked:

( ) was filed on _____ as US Application Serial No. or PCT International Application Number _____ and was amended on _____ (if applicable).

I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR 1.56.

Foreign Application(s) and/or Claim of Foreign Priority

I hereby claim foreign priority benefits under Title 35, United States Code Section 119 of any foreign application(s) for patent or inventor(s) certificate listed below and have also identified below any foreign application for patent or inventor(s) certificate having a filing date before that of the application on which priority is claimed:

COUNTRY	APPLICATION NUMBER	DATE FILED	PRIORITY CLAIMED UNDER 35 U.S.C. 119
			YES:___ NO:
			YES:___ NO:

Provisional Application

I hereby claim the benefit under Title 35, United States Code Section 119(e) of any United States provisional application(s) listed below:

APPLICATION SERIAL NUMBER	FILING DATE
60/186,312	3/2/2000

U.S. Priority Claim

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION SERIAL NUMBER	FILING DATE	STATUS(patented/pending/abandoned)

POWER OF ATTORNEY:

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) listed below to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Timothy H. Van Dyke, Reg. No. 43218 **Gerard H. Bencen, Reg. No. 35746**

Send Correspondence to:

Timothy H. Van Dyke
Bencen & Van Dyke, P.A.
1630 Hillcrest Street
Orlando, Florida 32803

Direct Telephone Calls To:

Timothy H. Van Dyke
407-228-0328

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Inventor: John R. Bianchi **Citizenship:** USA

Residence: 1 Innovation Drive, Alachua, Florida 32615

Post Office Address: Same

_____ _____

Inventor's Signature **Date**

DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION (continued)

ATTORNEY DOCKET NO. RTI-106

Full Name of Inventor: Kevin C. Carter Citizenship: USA

Residence: 1 Innovation Drive, Alachua, Florida 32615

Post Office Address: Same

Inventor's Signature Date

Full Name of Inventor: Citizenship:

Residence:

Post Office Address:

Inventor's Signature Date

Full Name of Inventor: Citizenship:

Residence:

Post Office Address:

Inventor's Signature Date

Full Name of Inventor: Citizenship:

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